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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/777,820

02/12/2004

Douglas A. Collins

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05/08/2006

EXAMINER

LUKTON, DAVID

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ART UNIT

PAPER NUMBER

1654

DATE MAILED: 05/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/777,820

Applicant(s)

COLLINS ET AL.

Examiner

David Lukton

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-71 is/are pending in the application.
- 4a) Of the above claim(s) 1-68, 70 and 71 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 69 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

In response to the "election of species" requirement mailed 1/30/06, applicants elected the following: (a) "compound 5" in figures 2 and 3, (b) water as the "pharmaceutically acceptable vehicle", (c) a method of treating a tumor without also imaging the tumor, and (d) the lungs as the anatomical location of the tumor.

Claims 1-71 remain pending. Claims 1-68 & 70-71 are withdrawn from consideration.



The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 69 is rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 69 is drawn to a method of treating cancer by administration of a compound which contains boron. For the treatment to be successful, however, localization at the site(s) of the tumor would be required. There are two issues here: (a) will the compounds of claim 1 sequester in cancerous tissue when the cobalamin moiety is intact? and (b) will the compounds of claim 1 sequester in cancerous tissue if only a "residue"

of the cobalamin is used?

As it happens, the answer to both questions is in the negative. It may be the case that the following claim is enabled:

100. A method of inhibiting the binding of cyanocolablin to a transcobalamin protein comprising contacting a compound according to claim 1 with a transcobalamin protein for a time and under conditions effective to inhibit the binding of cyanocolablin to the transcobalamin protein.

However, there is no reason to believe that any selective binding of the compounds to cancerous tissue will occur when the cobalamin moiety is intact, and certainly, there is no reason to believe that a small substituent such as acetamide or ethanol or phosphate will bind selectively to cancerous tissue. In the absence of selective binding, the skilled oncologist would not believe that an effective anti-tumor therapy can be achieved.

As stated in *Ex parte Forman* (230 USPQ 546, 1986) and *In re Wands* (8 USPQ2d 1400, Fed. Cir., 1988) the factors to consider in evaluating the need (or absence of need) for "undue experimentation" are the following: quantity of experimentation necessary, amount of direction or guidance presented, presence or absence of working examples, nature of the invention, state of the prior art, relative skill of those in that art, predictability or unpredictability of the art, and breadth of the claims.

In view of the absence of guidance, the absence of working examples, and unpredictability in the oncology field, the skilled artisan would conclude that "undue

experimentation" would be required to practice the claimed invention.



Claim 69 is rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- Claim 69 is dependent on a non-elected claim.
- In claim 69, the formula (of figure 1) should be provided.
- Claim 69 is indefinite as to the process steps of the "administering neutron capture therapy". What does the medical practitioner do, and what does he (or she) see? Does the neutron capture therapy require any external energy source? Does the neutron capture therapy require administration of a compound, either claimed or not claimed?
- Claim 69 is dependent on claim 1. Claim 1, in turn, is indefinite because of the absence of the indefinite article, i.e., claim 1 should begin with the following phrase:

A compound wherein ...



The following is a quotation of 35 USC. §103 which forms the basis for all obviousness rejections set forth in the Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made, absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

Claim 69 is rejected under 35 U.S.C. §103 as being unpatentable over Glass (USP 6017902)

Glass discloses various Boron-containing compounds for use treating tumors by neutron capture therapy.

Consider, for example, structure "A" of the patent (col 2, line 48+; col 14, line 47+).

The issue here is that which is meant by the term "residue" in instant claim 1. This term could be referring to any fragment of the compound depicted in figure 1 of the instant application. This could be, for example, ethanol. As it happens, ethanol (as a fragment) occurs in two locations in cyanocobalamin. And as it happens also, structure "A" of the patent contains an ethanol fragment. Instant claim 1 also requires the "residue" of the cyanocobalamin to be bonded, either directly or via a linker to a "molecule comprising B-10". Whether the linker is required or excluded, the structural requirements of claim 1 (and of claim 69) are met.



Claim 69 is rejected under 35 U.S.C. §103 as being unpatentable over Griffin (USP

5,630,786).

Griffin discloses various boron-containing compounds for use treating tumors by neutron capture therapy, such as the structures at col 7, line 36+.

This ground of rejection is based on the fact that a "residue" of cyanocobalamin can be just phosphate. The compounds of the reference qualify as a phosphate to which is bonded a molecule comprising boron.

Thus, the claim is rendered obvious.



Claim 69 is rejected under 35 U.S.C. §103 as being unpatentable over Schinazi (USP 5,599,796).

Schinazi discloses compound "F" at col 4, line 1+ and its use for boron neutron capture therapy. The pentose sugar qualifies as a "residue" of cyanocobalamin, and so the requirements of claim 1 are met.



Claim 69 is rejected under 35 U.S.C. §103 as being unpatentable over Collins (USP 6,004,533) in view of Schinazi (USP 5,599,796).

Collins discloses compounds in which cyanocobalamin is linked to a diagnostic radionuclide. Collins does not disclose compounds in which cyanocobalamin is linked to boron-10. Schinazi discloses compounds containing boron-10 in which cyanocobalamin

is linked to boron-10. Schinazi does not disclose that one of those compounds bearing B10 should be cyanocobolamin. However, it would have been obvious to one of ordinary skill to link B10 to cyanocobolamin to achieve the therapeutic benefits asserted by Schinazi.

Thus, the claim is rendered obvious.



- Reference “BR” was stricken from the IDS because of the absence of a translation
- Reference “FH” was stricken from the IDS because it was not received. Note that there may be an error; references FD and FH are both stated on the IDS to correspond to abstract # 500.
- Reference “EG” was stricken from the IDS because the citation is incomplete. For example, neither the title of the book, nor the year of publication has been provided.
- Reference “EO” was stricken from the IDS because the year of publication was not provided.
- The remaining references (apart from BR, FH, EG and EO) that were stricken from the IDS were so treated because they were not received.

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No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 571-272-0952. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can be reached at (571)272-0974. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

DAVID LUKTON, PH.D.
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read 'D. Lukton', is positioned below the printed name and title.